# UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

ALLEN MEMORIAL HOSPITAL CORPORATION; THE FINLEY HOSPITAL; and TRINITY REGIONAL MEDICAL CENTER, on behalf of themselves and all others similarly situated,

Civil Action	No	
CIVII /ICHOII /	110.	

Plaintiffs,

v.

JURY TRIAL DEMANDED

CSL LIMITED; CSL BEHRING LLC; and BAXTER INTERNATIONAL, INC.,

Defendants.

# **CLASS ACTION COMPLAINT**

Plaintiffs Allen Memorial Hospital Corporation, The Finley Hospital, and Trinity Regional Medical Center (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated (the "Class"), brings this action for treble damages under the antitrust laws of the United States against Defendants CSL Limited, CSL Behring LLC, and Baxter International, Inc. (collectively Defendants, unless separately identified), and demand a jury trial on all claims so triable.

## I. NATURE OF THE ACTION

1. Plaintiffs allege a multi-year nationwide conspiracy among Defendants and unnamed co-conspirators to restrict output and to fix, raise, maintain, or stabilize the prices of Plasma-Derivative Protein Therapies (defined below) sold in the United States.

- 2. Plasma-Derivative Protein Therapies are plasma-based products used to treat patients suffering from serious illnesses such as bleeding disorders and immune deficiencies.
- 3. Defendants develop, manufacture, and sell Plasma-Derivative Protein Therapies, which are used primarily by hospitals, such as Plaintiffs here, to treat critically ill patients suffering from, among other diseases, various immune disorders. The Plasma-Derivative Protein Therapies involved in the unlawful conduct alleged herein are Immune globulin ("Ig," "IGIV," or "IVIG") and Albumin.
- 4. Plaintiffs allege that Defendants conspired, combined, or contracted to restrict output and to fix, raise, maintain or stabilize the prices of Plasma-Derivative Protein Therapies that they sold to Plaintiffs and the other members of the Class during the Class Period a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. As a result of Defendants' unlawful conduct, Plaintiffs and the other members of the Class paid supracompetitive prices for Plasma-Derivative Protein Therapies, and thus suffered injuries of the type the federal antitrust laws are designed to prevent.
- 5. This lawsuit follows closely on the Federal Trade Commission's ("FTC") filing of an administrative complaint that sought to block CSL Limited's attempted acquisition of Talecris Biotherapeutics Holdings Corporation ("Talecris") a smaller manufacturer of Plasma-Derivative Protein Therapies on the grounds that the deal would substantially reduce competition in the United States for Plasma-Derivative Protein Therapies, among other products.
- **6.** Soon after the FTC filed its complaint, CSL chose to abandon its proposed Talecris acquisition.
- 7. In evaluating the anticompetitive effects that the deal would produce, the FTC discovered evidence from Defendants' own files that "suggests a strong possibility of ongoing

coordinated interaction between firms in the plasma industry." The FTC asserted that the redacted language in its Complaint "is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy," and thus could expose Defendants to "possible treble damages actions." CSL currently is attempting to prevent the FTC from making this language public.

- 8. The FTC's complaint describes, among other things, "troubling signs of coordinated behavior" that Defendants have undertaken, including "signaling," which is the intentional sharing of competitive information for purposes of seeking to ensure that manufacturers all are restraining output and curbing growth, thereby promoting higher prices.
- 9. In particular, Defendants have used specific key words to: (a) suggest to each other that increasing the production of Plasma-Derivative Protein Therapies could hurt the firms' ability to reap the significant profits that they all gained during an extended period where demand exceeded supply for these products; (b) remind each other of how, during a period when supply increased, prices and profitability for firms dropped substantially; and (c) encourage one another to increase supply only incrementally to keep pace with demand, and not increase supply to the extent the firms actually compete with one another for market share.
- 10. In an FTC press release accompanying the filing of the lawsuit, the Director of the FTC's Bureau of Competition stated that "[s]ubstantial consolidation has already occurred in the plasma protein industry, and these highly concentrated markets are already exhibiting troubling signs of coordinated behavior." Moreover, the FTC alleged that if the proposed acquisition were approved, Defendants "would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products."

- 11. As a result of the conspiracy, prices for Plasma-Derivative Protein Therapies were higher than they otherwise would have been. Beginning in 2005 and continuing through the present-day, prices for Plasma-Derivative Protein Therapies have increased substantially as a result of Defendants' allegedly unlawful conduct.
- 12. As a result of Defendants' unlawful conduct, Plaintiffs and the other members of the Class paid supracompetitive prices for Plasma-Derivative Protein Therapies and have suffered injury to their business and property. Seeking recovery for the financial harm that the conspiracy has inflicted, Plaintiffs bring this action on behalf of themselves and all other similarly situated those similarly situated that purchased Plasma-Derivative Protein Therapies in the United States directly from Defendants from October 1, 2004 through the present.

# II. JURISDICTION AND VENUE

- 13. Plaintiffs bring this action under Sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15 and 26, to recover treble damages and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries that Plaintiffs and the other members of the Class have suffered pursuant to Defendants' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.
- **14.** This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 1337 and Sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15(a) and 26.
- 15. Venue is proper in this District pursuant to 15 U.S.C. § 15(a) and 22 and 28 U.S.C § 139 1(b), (c) and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District. Moreover, Baxter, one of the named defendants, is headquartered in this District.

16. This Court has personal jurisdiction over each Defendant because each Defendant transacted business throughout the United States, including in this District; sold Plasma-Derivative Protein Therapies throughout the United States, including in this District; had substantial contacts with the United States, including in this District; or engaged in an illegal scheme and price-fixing conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

### III. PARTIES

## **Plaintiffs**

- 17. Allen Memorial Hospital Corporation ("Allen"), an affiliate of the Iowa Health System, is a nonprofit corporation organized under the laws of the State of Iowa, with its principal place of business located in Waterloo, Iowa. During the Class Period, Allen purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conduct alleged herein, Allen was injured in its business or property.
- 18. The Finley Hospital ("Finley"), an affiliate of the Iowa Health System, is a nonprofit corporation organized under the laws of the State of Iowa, with its principal place of business located in Dubuque, Iowa. During the Class Period, Finley purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conduct alleged herein, Finley was injured in its business or property.
- 19. Trinity Regional Medical Center ("Trinity"), an affiliate of the Iowa Health System, is a nonprofit corporation organized under the laws of the State of Iowa, with its principal place of business located in Fort Dodge, Iowa. During the Class Period, Trinity

purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conduct alleged herein, Trinity was injured in its business or property.

## **Defendants**

- 20. CSL Limited is a company incorporated and domiciled in Australia, with its principal place of business located at 45 Poplar Road, Parkville, Victoria, 3052, Australia. CLS Limited is the second-largest supplier of plasma-derivative protein therapies in the world. CSL Limited produces and sells biotherapies indicated for the treatment of several rare primary immune deficiency diseases, coagulation disorders, and inherited respiratory disease.
- 21. CSL Limited is a vertically integrated company. It owns and operates one of the world's largest plasma collection networks, CSL Plasma, with collection facilities and laboratories in Boca Raton, Florida and Marburg, Germany. It also owns and operates manufacturing sites, through its wholly-owned subsidiaries, in Marburg, Germany and Bern, Switzerland. CSL Limited's worldwide sales for its 2008 fiscal year were approximately \$2.5 billion 37% of which came from North America, including the United States.
- 22. CSL Behring LLC is a wholly-owned U.S. subsidiary of CSL Limited and is headquartered at 1020 First Avenue, King of Prussia, Pennsylvania 19406. CSL Behring is the second largest producer of Plasma-Derivative Protein Therapies in the United States. CSL Behring owns and operates more than 70 plasma collection facilities in the United States and Germany, and three plasma manufacturing centers, including one in Illinois. CSL Behring's 2008 sales revenue was approximately \$1.8 billion.
- 23. Baxter International Inc. is a global, diversified healthcare company that incorporated in Delaware and has its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Baxter is the largest producer of plasma-derivative protein therapies

in the world, and is the largest producer of Plasma-Derivative Protein Therapies in the United States – with 2008 revenues of more than \$12.3 billion, more than 33% of which came from its BioScience business segment, the Baxter division responsible for Plasma-Derivative Protein Therapies. Baxter's BioScience segment has 11 manufacturing sites domestically and abroad, including sites in Hayward, Thousand Oaks, and Los Angeles, California and in Beltsville, Maryland.

## IV. CO-CONSPIRATORS

- 24. Various other individuals, firms, and corporations, not named as defendants herein, may have participated as co-conspirators with Defendants and performed acts and made statements in furtherance of the conspiracy. Plaintiffs reserve the right to name subsequently some or all of these persons and/or entities as defendants.
- 25. Whenever in this Complaint reference is made to any act, deed, or transaction of any corporation, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the management, direction, control or transaction of the corporation's business or affairs.

## V. CLASS ACTION ALLEGATIONS

**26.** Plaintiffs bring this action on behalf of themselves and as a class action, pursuant to the provisions of Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure on behalf of the following Class:

All persons and entities in the United States who purchased Plasma-Derivative Protein Therapies directly from one or more of the Defendants or their co-conspirators at any time from at least October 1, 2004 through the present. Excluded from the Class are Defendants, their parent companies, subsidiaries and affiliates, any co-conspirators, federal governmental entities and instrumentalities

of the federal government, states and their subdivisions, agencies, and instrumentalities.

- 27. Plaintiffs believe that there are thousands of Class members, the exact number and their identities being known by Defendants, making the Class so numerous and geographically dispersed that joinder of all members is impracticable.
  - **28.** There are questions of law and fact common to the Class, including:
- (a) Whether Defendants and their co-conspirators engaged in a combination and conspiracy among themselves to restrict output and to fix, raise, maintain or stabilize the prices of Plasma-Derivative Protein Therapies sold in the United States;
  - (b) The identity of the conspiracy's participants;
- (c) The duration of the conspiracy alleged in this Complaint and the acts carried out by Defendants and their co-conspirators in furtherance of the conspiracy;
  - (d) Whether the alleged conspiracy violated Section 1 of the Sherman Act;
- (e) Whether the conduct of Defendants and their co-conspirators, as alleged in this Complaint, caused injury to the business and property of Plaintiffs and the other members of the Class;
- (f) The effect of the conspiracy on the prices of Blood Plasma Proteins sold in the United States during the Class Period; and
  - (g) The appropriate Class-wide measure of damages.
- 29. Plaintiffs' claims are typical of the claims of the other Class members. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs and the other Class members are similarly affected by Defendants' wrongful conduct in violation of the antitrust laws in that they paid supracompetitive prices for products purchased directly from Defendants or their con-conspirators. Plaintiffs' claims arise out of the same common course of conduct

giving rise to the claims of the other members of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other members of the Class.

- **30.** Plaintiffs are represented by counsel who are competent and experienced in the prosecution of antitrust and class action litigation.
- **31.** The prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.
- **32.** The questions of law and fact common to the members of the Class predominate over any questions affecting only individual Class members.
- 33. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable. Prosecution as a class action will eliminate the possibility of repetitious litigation. Treatment as a class action will permit a large number of similarly-situated persons to adjudicate their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would engender. This class action presents no difficulties in management that would preclude maintenance as a class action.

## VI. INTERSTATE TRADE AND COMMERCE

- **34.** The activities of Defendants and their co-conspirators, as alleged in this Complaint, were within the flow of and substantially affected interstate commerce.
- 35. During the Class Period, Defendants and their co-conspirators sold substantial quantities of Plasma-Derivative Protein Therapies in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

**36.** The conspiracy in which the Defendants and their co-conspirators participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

## VII. FACTUAL ALLEGATIONS

## **The Plasma-Derivative Proteins Industry**

- 37. The manufacturing process for plasma-derivative proteins involves: (a) plasma collection; (b) plasma testing; (c) fractionation (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.); (d) finishing or purification; (e) quality control; and (f) lot release. The time required to complete the full manufacturing process ranges from approximately seven months to one year.
- 38. The manufacturing process is highly regulated because plasma products run the risk of containing and transmitting infections. Regulatory bodies include the United States Food and Drug Administration ("FDA"), state regulatory agencies, and the Plasma Protein Therapeutics Association, an industry self-regulatory body.
- **39.** The FDA must approve plasma collection centers and the plants at which Plasma-Derivative Protein Therapies are made, as well as the therapies themselves.
- **40.** Plasma is a very expensive raw material, representing between 40 to 70% of the cost of Plasma-Derivative Protein Therapies.
- 41. As further explained below, the market has substantially consolidated over the past two decades. In 1990, there were thirteen Plasma-Derivative Protein Therapy manufacturers. In 2003, the number of Plasma-Derivative Protein Therapy manufacturers was reduced to nine. Today, only five Plasma-Derivative Protein Therapy manufacturers still exist: Baxter, CSL, and Talecris, as well as Grifols and Octapharma, two smaller manufacturers.

- **42.** The Federal Trade Commission ("FTC") has determined that the Plasma-Derivative Protein Therapies market operates as a "tight oligopoly."
- 43. The U.S. Department of Health and Human Services ("HHS") issued a report on the IGIV market in February 2007 entitled *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)* ("HHS Report"). One of its key findings was that Ig "manufacturing is a tight oligopoly in which the leading three manufacturers [CSL, Baxter and Talecris] . . . have a combined market share of around 85%."
- **44.** During the Class Period, demand for Plasma-Derivative Protein Therapies has exceeded supply. Indeed, according to the HHS Report, demand for IGIV has risen sharply over the last decade. The HHS Report found that "[t]he existence of a secondary market with high IGIV prices combined with a manufacturer instituted allocation system for IGIV are symptomatic of a market in which demand exceeds supply."
- **45.** Plasma-derivative proteins are essential for treating a number of serious illnesses, including immune deficiency diseases, coagulation disorders, and respiratory diseases. The annual cost for such treatments can exceed \$90,000 per patient in some cases.
- **46.** Purchasers of plasma-derivative proteins usually hospitals through contracts negotiated by Group Purchasing Organizations will pay very high prices if necessary to make treatment available to critically ill patients. Consequently, small changes in production levels cause dramatic swings in prices for products, and producers stand to increase profits greatly by controlling output relative to demand.
- 47. Control of supply is critical to preventing price competition. Limiting the supply of Plasma-Derivative Protein Therapies serves to raise prices. Correspondingly, a high degree of concentration facilitates the operation of a cartel, because it makes it easier to coordinate

behavior among possible co-conspirators and it makes it more difficult for customers to avoid the effects of the collusive behavior.

**48.** The most prominent plasma-derivative proteins are: (a) Ig; (b) albumin; (c) alpha-1; and (d) Rho-D. The relevant plasma-derivative protein products for purposes of this Complaint are Ig and albumin.

## **Relevant Product Markets**

Ιg

- **49.** Ig is a widely used drug that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the more predominant form, has more than twenty FDA-approved indications, and as many as 150 off-label uses.
- 50. Ig products are antibody-rich plasma therapies that long have been used in the treatment of primary immune deficiencies (to provide antibodies a patient is unable to make) and certain autoimmune disorders where it is believed to act as an immune modulator. In addition, physicians frequently prescribe Ig for a wide variety of diseases, although these uses are not described in the product's labeling and differ from those tested in clinical studies and approved by the FDA or other regulatory agencies in other countries. These unapproved, or "off-label," uses constitute the preferred standard of care or treatment of last resort for many patients in varied circumstances.
- 51. Ig represents the largest plasma-derived protein product by value. It is estimated that 70% of IVIG sold in the United States in 2007 was purchased by hospitals through contracts negotiated with GPOs, Physician offices represented about 13% of IGIV volume, and homecare companies and specialty pharmacies represented about 17% of IGIV volume.
- **52.** Ig constitutes a relevant product market.

# **53.** There are no good substitutes for Ig.

#### Albumin

- **54.** Albumin is the most abundant protein in human plasma. It is synthesized by the liver and performs multiple functions, including the transport of many small molecules in the blood and the binding of toxins and heavy metals, which prevents damage that they otherwise might cause. Albumin is used to expand blood volume and to prime heart values during surgery.
- **55.** Albumin generally is used in surgical and trauma settings and typically is sold to hospital groups.
  - **56.** Albumin constitutes a relevant product market.
- **57.** There are no good substitutes for albumin. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

## **Relevant Geographic Market**

- **58.** The relevant geographic market is the United States.
- 59. Like pharmaceutical products, each Blood Plasma Protein must be approved for sale in the United States by the FDA. To obtain approval, the products must be produced from plasma collected in the United States at collection centers approved by the FDA. The products also must be manufactured at plants approved by the FDA.
- 60. Performing the requisite clinical trials and undergoing the FDA approval process for plasma and plasma-derivative products, including Plasma-Derivative Protein Therapies, takes well over two years. Accordingly, Plasma-Derivative Protein Therapies sold outside of the United States are not viable competitive alternatives for United States customers, who cannot

buy these products even in the event of a price increase for products available in the United States.

## **Market Characteristics**

**61.** The structure and characteristics of the Plasma-Derivative Protein Therapies markets in the United States are particularly conducive to a price-fixing agreement, and have made collusion particularly attractive in this market. These factors are discussed below.

## Commodity-Like Products

- **62.** A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers both to agree on prices for the product and to monitor these prices.
- 63. Plasma-Derivative Protein Therapies are homogeneous, commodity-like products within a given product category (e.g., Albumin or Ig) and one Defendant's Plasma-Derivative Protein Therapies easily can be substituted for a Blood Plasma Protein made by the other Defendant.
- **64.** Indeed, Talecris, one of Defendants' competitors, noted in a 2008 SEC filing that "[a]mong albumin products, competition is generally based on price, given that the products tend to be homogeneous."
- **65.** Because Plasma-Derivative Protein Therapies are commodity-like products, purchasers make purchase decisions based predominantly, if not entirely, on price.

## Lack of Substitutes

- **66.** The lack of available substitutes for a product also helps facilitate an effective price-fixing conspiracy. Without substitutes, producers of the product can raise prices without losing significant sales to closely competing products.
- 67. For hospitals, physicians, and others that use Plasma-Derivative Protein Therapies, there simply are no suitable substitutes for these products, at any price. They must purchase Plasma-Derivative Protein Therapies regardless of the price; nothing else will do. Indeed, as Patrick Robert of the Marketing Research Bureau Inc. has noted, "therapeutic plasma proteins [including Plasma-Derivative Protein Therapies] remain essential life-saving drugs for which there is still no competitive drug."

# **Industry Concentration**

- 68. A high degree of concentration facilitates coordination among coconspirators. Defendants control a high percentage of the United States plasma-derivative protein industry, collectively possessing about a 60% market share. In particular, Baxter controls about 36% of the market, and CSL controls about 24% of the market. The remaining manufacturers, Talecris, Grifols USA ("Grifols"), and Octapharma USA, Inc. ("Octapharma"), possess shares of approximately 23%, 7% and 5%, respectively.
- 69. With respect to the domestic Ig market, according to 2008 sales volumes, Defendants collectively possess approximately a 62.9% market share. CSL has about a 27.5% market share, and Baxter has about a 35.4% market share. The remaining manufacturers, Talecris, Grifols, and Octapharma, possess shares of approximately 20%, 9%, and 7.2%, respectively.

- **70.** The market is highly concentrated, with a Herfindahl-Hirschman Index ("HHI") of 2,579. The HHI test is used by the FTC and DOJ to gauge market concentration. An industry with an RHI exceeding 1,800 is deemed "highly concentrated."
- **71.** With respect to the domestic albumin market, according to 2008 sales volumes, Defendants collectively possess approximately a 73.05% market share. CSL possesses about a 36.6 1% market share, and Baxter maintains about a 36.44% share. The remaining competitors, Talecris, Grifols, and Octapharma, possess shares of 8.83%, 13.06%. and 5.07%, respectively.
- 72. Throughout the Class Period, Defendants collectively possessed market power to raise prices above competitive levels in the Plasma-Derivative Protein Therapies markets in the United States without losing appreciable market share to non-conspirators.

### **Barriers** to Entry

- 73. The presence of significant entry barriers to potential competitors that could otherwise cause the incumbents to reduce their prices helps facilitate coordination among coconspirators.
- **74.** The market for Plasma-Derivative Protein Therapies is characterized by high entry barriers. Indeed, no firm has entered de novo in recent history, and prospective entrants have little chance of making a meaningful market impact in a timely fashion.
- **75.** Each step of the manufacturing process for Plasma-Derivative Protein Therapies involves substantial up-front, sunk costs, onerous and lengthy regulatory approvals by federal and state agencies, and specialized technical know-how and expertise.
- **76.** Entry into the Plasma-Derivative Protein Therapies markets requires a significant amount of intellectual property, including trade secrets relating to purification of products and pathogen safety, and substantial product research and development.

- 77. Regulatory hurdles impose significant barriers to entry and extend the time it would take to enter the United States markets, let alone make a significant impact in the markets.
- **78.** In addition, the construction and maintenance of production facilities, including regular improvements necessitated by evolving standards of manufacturing practices, requires extensive capital expenditures and may involve long lead times to obtain the necessary governmental approval.
- 79. Any new competitors in the United States also would need to secure an adequate supply of domestic plasma because only plasma collected in the United States is certified for use in products sold domestically. Because there currently are only a very limited number of independent plasma suppliers, most of whose plasma collection and center development capacity is already contracted to existing manufacturers, any new competitor likely would have to develop its own domestic-based plasma collection centers and related infrastructure.

## **Demand Inelasticity**

- **80.** Price elasticity of demand is the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue. Inelastic demand is another indicator that a price-fixing conspiracy would be successful.
- **81.** The demand for Plasma-Derivative Protein Therapies is highly inelastic. Plasma-Derivative Protein Therapies are considered medical necessities that must be purchased by hospitals, physicians, and others at whatever the cost. Moreover, there are no close substitutes for these products.

## Opportunity for Conspiratorial Communications

- **82.** Defendants are members of trade associations and regularly attend meetings together.
- Association ("PPTA"). The PPTA is "the primary advocate for the world's leading source plasma collectors and producers of plasma-based and recombinant biological therapeutics." Defendants are Global, North American, and European Members of the association, and their high-level executives, including Peter Turner, President of CSL Behring, and Larry Guiheen, President of Baxter BioScience, serve on the association's Global Board of Directors. Mr. Turner also serves as the association's president. The PPTA convenes its annual meeting, known as the Plasma Protein Forum, in June in the Washington, D.C. metropolitan area, and high-level executives from Defendants, such as Messrs. Turner and Guiheen, routinely attend.
- **84.** Such trade association meetings provide the opportunity for participants in price-fixing conspiracies such as this one to meet, have improper discussions under the guise of legitimate business contacts, and perform acts necessary for the operation and furtherance of the conspiracy.

## Market Dynamics During Late 1990's-Early 2000's

**85.** In the late 1990's, a series of events brought about by temporary plant closures, following FDA intervention, resulted in extensive change in supply for both the domestic and global plasma-derivative protein products industries.

- **86.** In 1997, in the wake of a recall of albumin produced by a company called Centeon, the FDA mandated the temporary closure of the plant then owned by Centeon at Kankakee, Illinois (which CSL Limited now owns).
- **87.** In 1999, the Alpha Therapeutic Corporation plant in Los Angeles, California (which CSL Limited also now owns) was temporary closed.
- **88.** The shortages that resulted from these disruptions, particularly concerning Ig supply, caused higher prices in the United States market, spurring producers to increase plasma collections as well as output of Plasma-Derivative Protein Therapies.
- 89. Between 2000 and 2003, however, once the Kankakee and Los Angeles facilities had recommended production, there was an oversupply of Plasma-Derivative Protein Therapies. This led to dramatic price declines and, in turn, to a 30% reduction in gross operating margins among producers. Due to fixed costs representing a high proportion of the total costs of Plasma-Derivative Protein Therapies production, this translated into a significant downturn in profits for the industry.
- **90.** This period of excess supply, in turn, resulted in another significant change in the industry, causing the remaining producers to reduce production and plasma collection capacity and to begin in earnest to vertically integrate.

#### **Industry Consolidation**

**91.** In 1990, there were 13 producers of plasma-derivative protein products. In 2003, that number dropped to nine. Since 2005, there have been only five: CSL, Baxter, Talecris, Grifols, and Octapharma.

- **92.** Several firms recently merged or were acquired. The large, integrated suppliers, most notably Defendants, have acquired numerous independent plasma collectors and facilities, and continue to do so. And soon after acquiring them, Defendants shut down many of them.
- 93. CSL Limited acquired the Swiss Red Cross fractionator, ZLB, as well as 47 plasma collection centers from Nabi, in July 2000. It acquired Aventis Behring's plasma products business in 2003. CSL Limited subsequently closed 35 plasma collection centers in the United States, reduced plasma collections by one million liters, and reduced plant output by 1.1 million liters.
- **94.** Baxter acquired 42 plasma collection centers and a laboratory from Alpha Therapeutic Corporation (Mitsubishi Pharma) in late 2002. Baxter subsequently closed 26 of its own plasma collection centers and 38 collection centers that it acquired from Alpha Therapeutic, as well as a plant in Rochester, Michigan.
- 95. As one investment firm with knowledge of the industry has noted, "[a]bout 80% of the [plasma collection] centers are now owned by plasma-products companies such as Baxter International, CSL Limited, Grifols, and Talecris Biotherapeutics. This represents a complete reversal in ownership since 2000, when 80% of the centers were independent enterprises."
- **96.** In 2005, a major non-profit entity, the American Red Cross, exited the plasma products industry.
- **97.** The plasma products industry as it now exists has significantly fewer suppliers than it did even six years ago. The remaining suppliers, most notably among them Defendants, are larger and more vertically integrated than ever before.

## **The Conspiracy**

- **98.** As consolidation has occurred in the plasma-derivative protein products industry, supply has been limited in the face of increasing demand, and prices consequently have increased in recent years, GPOs, hospitals, physicians and ultimately patients have experienced tightening supplies and rising prices. The restriction of supply and increase in prices for Plasma-Derivative Protein Therapies began in 2005 and has continued through the present.
- 99. The restriction of supply and increase in prices was not the result of natural market forces. Rather, they were caused by Defendants' conspiracy, which Defendants formed in response to the excess supply that occurred earlier in the decade and that Defendants did not want to experience again.
- 100. Indeed, Baxter explained in a recent investor call how competitors have "lived through the events of the early 2000's," referring to the period of excess supply and lower prices, and now have returned to a time of "very good stock prices and very good returns for shareholders." Similarly, at the 2007 Plasma Protein Forum, held June 5-6 at the Hyatt Regency in Reston, Virginia, and attended by numerous industry executives, including those of Defendants, Peter Turner, PPTA Chairman and President of CSL Behring, "declared the industry to be in 'good shape' after a few bumps in the road in years past."
- 101. Defendants implemented their illegal agreement by coordinating and restricting output and by signaling to one other and to other competitors to do the same. Indeed, during and after the period of excess capacity earlier in the decade, Defendants recognized that controlling capacity was critical to preventing price competition.

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- 102. A key element of the conspiracy was Defendants' focus on the prevention of oversupply of Plasma-Derivative Protein Therapies and plasma in the marketplace. For example, Baxter has recognized that as long as competitors are not "irrational" and do not "trash price and take share," then they can increase supply steadily in line with market demand to keep prices high.
- 103. Competitive information is widely available from industry sources and the competitors themselves, Firms closely monitor each others' activities with respect to plasma collection, manufacturing, and output, and firms collect and catalogue an extraordinary wealth of timely competitive information.
- Defendants have taken advantage of this timely competitive information not only 104. by monitoring their competitors' activities, but also by engaging in signaling – the intentional sharing of competitive information for purposes of seeking to ensure that manufacturers all are restraining output, curbing growth, and maintaining high prices.
- In particular, Defendants have used specific key words to: (a) suggest to each 105. other that increasing the production of Plasma-Derivative Protein Therapies could hurt the firms' ability to reap significant profits that they all gained during an extended period where demand exceeded supply for these products; (b) remind each other of how, during a period when supply increased, prices and profitability for firms dropped substantially; and (c) encourage one another to increase supply only incrementally to keep pace with demand, and not increase supply to the extent the firms actually compete with one another for market share.
  - Baxter's CFO acknowledged Defendants' signaling in a recent investor call: 106.
  - "Why any of us would, for a very short-term gain, do anything to change [the current marketplace dynamics. I just don't see why we would. It wouldn't make any sense and from everything we read and all the signals we get, there is nothing

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that says anyone would do that. I think people are very consistent in the messages they deliver, which are pretty consistent with what we have told you today."

- 107. Another aspect of the conspiracy was the rationing of supply to purchasers. In 2006, the Department of Health and Human Services ("HHS") investigated reports that patients were experiencing problems purchasing Ig. HHS stated that Ig [m]anufacturers are currently allocating IGIV to their customers. Under this allocation system, most customers are expected to justify their current IGIV use to the manufacturer to maintain and/or increase their allocations. In economic terms, current IGIV supplies are being rationed." HHS also noted that "[t]he existence of a secondary market with high IGIV prices combined with a manufacturer instituted allocation system for IGTV are symptomatic of a market in which demand exceeds supply." HHS concluded that a majority of hospitals surveyed could not purchase enough IGIV to meet all of their patient needs, and calculated that the shortfall of supply relative to demand was approximately 14%.
- 108. Defendants have explored means of punishing firms, most notably Talecris, that have attempted to buck the prevailing restrained industry approach by increasing output.
- 109. Talecris is the one firm in the industry that potentially could thwart the prevailing restrained approach that Defendants successfully have advocated and implemented thus far. Indeed, according to the FTC, Talecris is "the one firm that has consistently and significantly expanded output in the United States." Moreover, Talecris recently stated in a 2008 SEC filing that it "intend[s] to serve the overall market growth with incremental increases in production capacity" in 2008 and 2009.
- In a further attempt to reduce industry production capacity and maintain high prices and margins, CSL Limited recently attempted to acquire Talecris. In an unusual move for a company whose competitor was contemplating a key acquisition, Baxter publicly expressed its

view that CSL Limited's attempted acquisition of Talecris would be "a positive stabilizing move within the industry." The FTC subsequently sought to block the attempted acquisition. (The FTC action is discussed in depth below).

- 111. Defendants' agreement to restrict supply and raise prices has been assisted by increased industry consolidation and the resulting oligopolistic market structure. The remaining participants have recognized that they are operating in an oligopoly where they are better off avoiding competition, restricting supply, and raising prices.
- **112.** Defendants' conspiracy has worked. Beginning in 2005 and continuing through the present, prices for Plasma-Derivative Protein Therapies consistently have increased.
- 113. The average sales price for a gram of IVIG has increased from about \$47.60 in 2005 to about \$57 in 2009, according to an analyst presentation that Grifols gave on March 5, 2008. The same presentation stated that "IVIG, which remains the driver of the plasma derivatives market, has witnessed price increases since 2005, coinciding with increased demand related to product availability."
- 114. The average sales price for a gram of albumin has increased from about \$1.25 in 2005 to about \$2.20, according to the same Grifols presentation. The presentation also reports that "average albumin prices have steadily increased since 2005 from U.S. \$14 to around U.S. \$35 per 12.5 g. vial at present." A Talecris 2008 SEC filing similarly notes that "[p]rices for albumin have increased significantly since 2005. . . The average selling price in 2007 was \$28.55, having grown at a CAGR of 35% since 2005, when the U.S. average selling price (ASP) was \$15.58."
- 115. Defendants' contemporaneous business reports have borne out these facts. For example, CSL Limited reported in its October 2004 Annual General Meeting presentation:

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"IVIG - prices have been stable with upward pressure going forward; currently experiencing solid demand;" and "Albumin - prices stable after period of weakness; inventory oversupply reducing."

- 116. In its October 2005 Annual General Meeting presentation, CSL Limited remarked that "US IVIG pricing environment improving," and that with respect to the CSL Behring, it is "managing plasma throughput to match: run down in inventory benefit; reduction of inventory levels; [and] demand." The Chairman's Address from the same 2005 meeting stated that CSL "Behring is well positioned to develop its global business through," among other things, "an effective balance between supply and demand." And in its October 2006 Annual General Meeting presentation, CSL Limited noted both that the "strong global demand for plasma therapies continues," and "plasma sector stability."
- 117. Defendants' conspiracy has resulted not only in supracompetitive pricing, but also extraordinary profits for Defendants, even as most other industries have experienced drastically lowered earnings in the face of the global economic crisis.
- 118. According to a March 2009 report issued by CSL's chairman, CSL experienced a post-tax net profit of \$502 million for the half-year ended December 31, 2008, an increase of 44% from the same period last year. The report also notes that "[t]he global financial crisis has had little to no impact so far on sales of CSL's portfolio of life saving therapies and essential vaccines . . . . [a]nd we anticipate broadly stable market conditions to continue."
- 119. CSL Behring sales revenue increased 33% to \$1.8 billion compared with the same period the previous year, "with strong contributions from both core and specialty plasma products," according to the same March 2009 CSL report.

120. Revenues from Baxter's BioScience unit climbed 12% to \$1.36 billion in 2008, largely pursuant to sales of plasma-based hemophilia and immune disorder treatments, vaccines and biosurgery products, Due to the profit its BioScience unit has generated, one news article has noted that "Baxter is one of a handful of stocks that have proven somewhat resistant to the global recession."

## **The Government's Antitrust Investigation**

- **121.** The FTC recently investigated the Plasma-Derivative Protein Therapies market and uncovered evidence suggesting the existence of an illegal price-fixing conspiracy.
- 122. The circumstances surrounding the FTC's investigation involved a potential acquisition by CSL of Talecris. Pursuant to an Agreement and Plan of Merger, dated August 12, 2008 ("Agreement"), CSL proposed to acquire all of the outstanding voting securities of Talecris in a transaction valued at \$3.1 billion.
- **123.** The proposed acquisition was reviewed for potential anticompetitive effects by the FTC.
- 124. On March 27, 2009 following an eight month investigation, which included the collection of testimony and declarations from twenty-one witnesses the FTC authorized a lawsuit to block CSL Limited's proposed \$3.1 billion acquisition of Talecris, charging that the deal would be illegal and substantially would reduce competition in the United States markets for Ig, albumin, Rho-D, and Alpha-i. On the same day, the FTC also sought a preliminary injunction in federal district court in the District of Columbia to stop the transaction pending completion of an administrative trial.
- 125. In an FTC press release accompanying the filing of the lawsuit, Richard Feinstein, Director of the FTC's Bureau of Competition, stated that "[s]ubstantial consolidation has already

occurred in the plasma protein industry, and these highly concentrated markets are already exhibiting troubling signs of coordinated behavior,"

- 126. The FTC described in its complaint, among other things, "troubling signs of coordinated behavior," including Defendants' signaling, product rationing, and other public statements and actions indicative of anticompetitive conduct.
- 127. The FTC alleged that, "with the elimination of Talecris the one firm that has consistently and significantly expanded output in the United States CSL and Baxter International, Inc. ("Baxter") would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products, to the great detriment of consumers."
- 128. Numerous sentences and parts of sentences from the FTC complaint have been redacted from public viewing. The FTC has moved to file an unredacted version of its complaint.
- 129. The FTC has stated that the redacted "language suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry. Evidence of transparency, interdependence, and signaling among firms is particularly relevant to the allegations in this matter. The language at issue bears on these very important points, and demonstrates how firms used specific key words to:
  - suggest to each other that increasing the production of lifesaving drugs could hurt the firms' ability to reap the significant profits they all achieved during an extended period where demand exceeded supply for the key products;
  - remind each other of how, during a period when supply increased, prices and profitability for the firms in the market dropped significantly; and

- encourage each other to only increase supply incrementally to keep pace with demand, not increase supply to the extent the firms actually compete with each other for market share."
- 130. The FTC also has noted that the redacted "quoted language . . . is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy. *See, e.g., In re High Fructose Corn Syrup Antitrust Litigation*, 295 F.3d 651, 662 (7th Cir. 2002) (Posner, J.) (referring to competitor as a 'friendly competitor,' mentioning an 'understanding between the companies that causes [them] not to . . make irrational decisions,' and querying whether competitors 'will play by the rules (discipline)' can all be evidence of an explicit agreement to fix prices)."
- 131. CSL Limited has opposed the FTC's motion to file an unredacted version of the complaint, claiming that every quote in the complaint derived from the respondents' documents constitutes confidential business information, and that disclosure of this information irreparably would harm their reputations. The FTC has responded by stating that the redacted material does not qualify as confidential business information, and that while disclosure of the material would cause "embarrassment" and "could 'expose respondent to possible treble damages actions," those reasons are not sufficient to prevent disclosure.
- 132. Shortly after the filing of the FTC complaint, on June 8, 2009, CSL Limited and Talecris publicly announced that they would abandon the proposed merger. On June 15, 2009, the FTC and the two firms jointly filed a motion to dismiss the FTC's complaint on that basis, and on June 22, 2009, the FTC dismissed the complaint.
- 133. There has been no ruling yet on the FTC's motion to file an unredacted version of the complaint. Significantly, the FTC has not abandoned its position, and believes that the public interest would best be served by full disclosure of the redacted language.

## VIII. ANTITRUST VIOLATIONS

- 134. Beginning at least as early as October 1, 2004, and continuing through the present, Defendants and their co-conspirators engaged in a continuing agreement, understanding, and conspiracy in restraint of trade to restrict output and to artificially raise, fix, maintain, or stabilize the prices of Plasma-Derivative Protein Therapies in the United States.
- 135. Based on the foregoing, and on information and belief, in formulating and effectuating the contract, combination, or conspiracy, Defendants and their coconspirators engaged in anticompetitive activities, the purpose and effect of which were to restrict output and to artificially raise, fix, maintain, or stabilize the price of Plasma-Derivative Protein Therapies sold in the U.S. These activities included:
  - (a) Defendants participating in conversations or communications to discuss the supply and price of Plasma-Derivative Protein Therapies in the United States;
  - (b) Defendants agreeing during those conversations or communications to restrict output and to charge prices at specified levels and otherwise to increase or maintain prices of Plasma-Derivative Protein Therapies sold in the United States; and
  - (c) Defendants agreeing during those conversations or communications to restrict output and to fix or stabilize prices of Plasma-Derivative Protein Therapies sold in the United States.
- **136.** Defendants and their co-conspirators engaged in the activities described above for the purpose of effectuating the unlawful agreements described in the Complaint.
- 137. Throughout the Class Period, Plaintiffs and the other members of the Class purchased Plasma-Derivative Protein Therapies from Defendants (or their subsidiaries or controlled affiliates) or their co-conspirators at supra-competitive prices.

138. Defendants' contract, combination, or conspiracy constitutes an unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

## IX. EFFECTS OF THE CONSPIRACY

- 139. As a result of Defendants' unlawful conduct, Plaintiffs and the other members of the Class have been injured in their business and property because they have paid more for Plasma-Derivative Protein Therapies than they would have paid in a competitive market.
- **140.** The unlawful contract, combination or conspiracy has had at least the following effects:
  - (a) price competition in the markets for Plasma-Derivative Protein Therapies has been artificially restrained;
  - (b) prices for Plasma-Derivative Protein Therapies sold by Defendants have been raised, fixed, maintained, or stabilized at supra-competitive levels; and
  - (c) purchasers of Plasma-Derivative Protein Therapies from Defendants have been deprived of the benefit of free and open competition in the Plasma-Derivative Protein Therapies markets.

#### X. FRAUDULENT CONCEALMENT

- **141.** Plaintiffs and the other members of the Class did not discover, and could not have discovered through the exercise of reasonable diligence, the existence of the conspiracy alleged herein until May 27, 2009, when the FTC's redacted complaint was filed.
- 142. Because Defendants' alleged conspiracy was kept secret until May 27, 2009, Plaintiffs and the other members of the Class, before that time, were unaware of Defendants' unlawful conduct alleged herein, and they did not know before that time that they were paying

supra-competitive prices for Plasma-Derivative Protein Therapies throughout the United States during the Class Period.

- 143. Defendants' affirmative acts, as alleged herein, including acts in furtherance of the conspiracy, were wrongfully concealed and carried out in a manner that precluded detection.
- 144. By their very nature, Defendants' conspiracy was inherently self-concealing. Plasma-Derivative Protein Therapies are not exempt from antitrust regulation, and thus, before May 27, 2009, Plaintiffs reasonably considered it to be a well-regulated, competitive industry.
- 145. In the context of the circumstances surrounding Defendants' pricing practices, Defendants' acts of concealment were more than sufficient to preclude suspicion by a reasonable person that Defendants' pricing was conspiratorial. Accordingly, a reasonable person under the circumstances would not have been alerted to investigate the legitimacy of Defendants' proffered Plasma-Derivative Protein Therapies prices before May 27, 2009.
- 146. Plaintiffs and the other members of the Class could not have discovered the alleged conspiracy at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by Defendants and their coconspirators to avoid detection of and fraudulently conceal their conspiracy.
- **147.** Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiffs and the other members of the Class had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, until May 27, 2009, when the FTC complaint, and its corresponding factual allegations of anti-competitive conduct concerning Plasma-Derivative Protein Therapies, was first publicly disseminated.

- 148. None of the facts or information available to Plaintiffs and the other members of the Class prior to May 27, 2009, if investigated with reasonable diligence, could or would have led to the discovery of the conspiracy alleged herein prior to that date.
- 149. As a result of Defendants' fraudulent concealment of their conspiracy, the running of any statute of limitations has been tolled with respect to any claims that Plaintiffs and the other members of the Class have alleged in this Complaint.
- **150.** Defendants and their co-conspirators engaged in a successful anti-competitive conspiracy concerning Plasma-Derivative Protein Therapies, which they affirmatively concealed, at least in the following respects:
- (a) By communicating secretly to discuss output and prices of Blood Plasma Proteins in the United States; and
- (b) By agreeing among themselves not to discuss publicly, or otherwise reveal, the nature and substance of the acts and communications in furtherance of their illegal scheme.
- **151.** As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiffs and the Class' claims have been tolled.

## XI. <u>CLAIMS ALLEGED</u>

# COUNT I <u>VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1)</u>

- **152.** Plaintiffs incorporate and reallege each of the preceding allegations.
- 153. Beginning at least as early as October 1, 2004, and continuing through the present-day, Defendants and their co-conspirators, by and through their officers, directors, employees, agents, or other representatives, entered into a continuing agreement, understanding, and conspiracy in restraint of trade to restrict output and to artificially raise, fix, maintain, or

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stabilize prices for Plasma-Derivative Protein Therapies in the United States in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

- 154. Plaintiffs and the other members of the Class have been injured in their business and property by reason of Defendants' unlawful combination, contract, conspiracy and agreement.
- 155. Plaintiffs and the other members of the Class have paid more for Plasma-Derivative Protein Therapies than they otherwise would have paid in the absence of Defendants' conduct.
- **156.** This injury is of the type the federal antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

## XII. REQUEST FOR RELIEF

**WHEREFORE**, Plaintiffs respectfully request that the Court grant the following relief:

- That the Court determine that this action may be maintained as a class action A. under Rules 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, that Plaintiffs be appointed as class representatives, and that Plaintiffs' counsel be appointed as class counsel;
- B. That the unlawful conspiracy alleged in Count I be adjudged and decreed to be an unreasonable restraint of trade or commerce, in violation of Section 1 of the Sherman Act;
- C. That Plaintiffs and the other members of the Class recover the damages determined to have been sustained as to each of them, trebled as provided by law, and that judgment be entered against Defendants, jointly and severally, on behalf of Plaintiffs and each of the other Class members;
- That Plaintiffs and the other members of the Class recover their costs of the suit, D. including attorneys' fees, as provided by law; and

E. That the Court direct such further relief it may deem just and proper.

# XIII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demands a jury trial as to all claims and issues so triable.

Dated: September 11, 2009

Respectfully submitted,

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